

Effectiveness and complications of primary C-clamp stabilization or external fixation for unstable pelvic fractures

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1 HIGHLIGHTS

1. Initial use of C-clamp or external fixation for unstable pelvic fractures is associated with a decreased mortality.
2. These emergency measures are not an independent risk factor for complications after secondary surgery.
3. The risk for infection after ilio-sacral screw fixation was almost 5-fold increased when primarily a C-clamp was used.
4. In conclusion, emergency stabilization of pelvic fractures is a safe procedure which potentially can save lives.
5. However, the risk for ilio-sacral screw implantation after C-clamp use should be evaluated cautiously.

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1 ABSTRACT

Background and purpose

Unstable pelvic fractures frequently require emergency stabilization using a C-clamp or external (CC/EF) fixation. However, the effectiveness of this intervention and associated complications are still a matter of debate.

Patients and methods

The analysis used data available from the German Pelvic Trauma Registry to study general complications, infections and mortality after primary stabilization using CC/EF in 5,499 patients (n=957 with vs n=4,542 without). Furthermore, the subgroups with secondary surgery (n=713 vs n=1,695), and ilio-sacral screw implantation following C-clamp stabilization were evaluated (n=24 vs n=219). Calculated odds ratios were adjusted for potential confounders.

Results

Patients treated by CC/EF were younger (45 ± 20 vs 62 ± 24 years), had more C-type fractures (65% vs 28%), higher ISS (≥ 25 63% vs 20%) and displacement (≥ 3 mm 81% vs 41%), and more complex fractures (32% vs 5%). These features were independent risk factors for complications ($p < 0.001$). While mortality was reduced after CC/EF stabilization by 32% (OR 0.68 95%CI 0.49-0.95), the risk for general complications was slightly increased (OR 1.25 95% CI 1.02-1.53). In patients undergoing secondary surgery, CC/EF fixation had no influence on mortality, general complications or infections. Related to preceding C-clamp stabilization (OR 4.67 95% CI 1.06-20.64), the risk for infection increased from 3.2% to 20.8% in ilio-sacral screw fixation.

Interpretation

Primary stabilization of unstable pelvic fractures with C-clamp or external fixation is associated with a decreased mortality and was not an independent risk factor for complications after secondary surgery. However, the risk for infection after ilio-sacral screw fixation increased almost 5-fold after C-clamp use.

2 INTRODUCTION

Unstable pelvic fractures often require emergency stabilization using a C-clamp or external fixation [1]. These measures are thought to be effective in stopping haemorrhage, however, they also have potential side effects. While some studies identified independent risk factors for infections in pelvic fractures such as degree of instability [2], embolization [3] or laparotomy [4]; other trials found no association between re-operations and patient's treatment or other injury-associated factors [5]. It is still a matter of debate whether a primary stabilization with C-clamp or external fixation changes the complication pattern or increases the risk of local infections. This is especially interesting and likely because the incisions necessary for both procedures often interfere with later needed surgical approaches.

The purpose of this study was to assess the effectiveness of primary C-clamp stabilization or external fixation for unstable pelvic fractures and associated complications using data from the German Pelvic Trauma Registry. We hypothesized that C-clamp stabilization and external fixation enhance the risk for complications and infections compared with patients without need for these emergency interventions. Concurrently, we expected that the adjusted risk for mortality would be the same in both groups

because the emergency stabilization should compensate the per se increased instability of patients requiring treatment by C-clamp or external fixation.

3 METHODS

This was a cross-sectional study evaluating registry data designed to answer the following research questions:

Q1: How often and in which population are C-clamp stabilization or external fixation used as emergency measures in the treatment of type B and C pelvic fractures?

Q2: Is there a difference between patients who are treated by C-clamp or external fixation or not?

Q3: Is the frequency of general complications, infections and in-hospital death higher in the group treated primarily with external fixation or C-clamp compared with the other patients after correcting for potential confounders?

Q4: Does an emergency stabilization with C-clamp or external fixation increase the complication and infection rate after secondary surgery?

Q5: In the sub-group of patients with implantation of ilio-sacral screws for ilio-sacral or sacral instability, is there a higher infection rate after C-clamp use?

3.1 PELVIC TRAUMA REGISTRY INITIATIVE

Within the Pelvic Trauma Registry Initiative, data from patients with blunt and penetrating pelvic fractures are collected prospectively. The group includes a consortium of trauma departments from 29 university hospitals and level I trauma centres [6–8]. The participating hospitals are required to register all treated cases, which are approved on a yearly basis. Documentation guidelines are supervised by a steering group and communicated during regular meetings twice a year. Data anonymity is guaranteed for the patient and participating hospital. From 2004 (pilot phase from 2001), a secured internet interface hosted by a professional service provider (Swiss medical Registries and Data Linkage, University of Bern, Switzerland) facilitated data management including processing and plausibility checks. Data acquisition and analysis were done in accordance with ethical guidelines and approved by our institutional review board (no. 89/09). The trial was registered at the German Clinical Trials Register (no. 00000488).

3.2 PATIENT SELECTION

The analysis used data available from the German Pelvic Trauma Registry with an extraction date of 4 November 2016. Patients were eligible for analysis if they had a B- or C- type pelvic fracture treated at a participating center from the time of registry inception until 6 Oct 2016. Unstable fractures involving only the sacrum were excluded because in these cases neither C-clamp nor external fixation were used. All patients meeting the inclusion criteria were included in the analysis.

3.3 STATISTICAL METHODS

The outcomes of interest included complications (any general, any infection), and death analyzed as binary variables and registered during the whole hospital stay from admission to discharge. As recently described [9], general complications included thrombosis, embolism, Adult Respiratory Distress Syndrome (ARDS), Multiple Organ Failure (MOF), neurological deficits, bleeding, hematoma, seroma, wound healing problems, implant loosening, implant failure, secondary displacement, and a category "Other".

All analyses were adjusted for age and gender. Additional variables assessed as risk factors and potential confounders included fracture type (B or C), Injury Severity Score (ISS), maximum displacement (derived as the maximum of all displacement variables in mm), laparotomy, embolization, complex fracture, and department case-load of the treating hospital. ISS was treated as a categorical rather than a continuous variable as there are some values that are not possible due to how the score is calculated; categories were based on previous published work [10]. The lowest categories were combined due to low patient numbers with ISS from 4-9. Laparotomy was dichotomized and coded "yes" if a preperitoneal pelvic packing was carried out; missing values were analyzed as "no". Embolization was coded "yes" if angioembolization was carried out as described earlier [11]; missing values changed to "no". Complex fractures were coded for concomitant internal pelvic injuries or open fractures. Department case-load was assessed as categorical variable defined by institutions with <500, 500-999, or 1000-1500 of the study population enrolled.

The crude odds ratios (OR) and corresponding 95% confidence intervals (CIs) were calculated for both models. Significance level was set at $\alpha=0.05$ for all comparisons.

Bi-variate analysis was used to assess the possible confounding variables by calculating the OR for each outcome adjusted for each potential risk variable individually in turn. Additional variables changing the OR for each outcome by 10% or greater were considered potential confounders and tested for inclusion in the final multivariable logistic regression model. Age and gender were considered a priori risk factors for all outcomes and included in all regression models.

Two models were used to answer the research questions. Model 1 compared outcomes for patients treated with or without external fixation or C-clamp. Model 2 compared outcomes for the same groups of patients that underwent secondary surgery. ORs and CIs were calculated in both models for the outcomes general complications, any infections, and death. A subgroup analysis of Model 2 compared the infection rate following IS-screw implantation after C-clamp stabilization or without. Patients with missing data for variables used to determine eligibility or adjustment for confounding (<10%) were also excluded from the analysis. All analyses were completed using STATA, version 14 (StataCorp LLC, College Station, TX, USA).

4 RESULTS

4.1 STUDY POPULATION AND BASELINE CHARACTERISTICS

Between March 2001 and October 2016, 5499 patients met the study inclusion criteria and were included in the analysis (Figure 1). Data records were complete for all variables required for the analysis comparing patients treated with (n=957, 17.4%) or without C-clamp stabilization or external fixation (n=4542, 82.6%) ("Model 1"). Of the patients treated by one of the emergency measures, 713 had secondary surgery (74.5%) whereas in the other group 1695 were later operated counting for only 37.3% ("Model 2").

Baseline characteristics of patients included in Model 1 are presented in Table 1. Overall, patients included had a mean age of 59 ± 24 years, with patients treated by emergency stabilization having a mean age approximately 17.5 years younger than those receiving non ($p<0.001$). Almost 60% of the patients were female, but a higher proportion of men needed pelvic clamp or external fixation (64.7%) compared with the group without (36.3%). There were 3626 (65.9%) of patients with B-type fracture and 1873 (34.1%) with C-type fractures included. Patients treated with stabilizing emergency measures had also a higher chance to undergo emergency measures to stop active haemorrhage such as a laparotomy for pelvic packing and selective embolization ($p<0.001$). Furthermore, they were generally more likely to have higher ISS (injury severity score), and larger maximum displacement ($p<0.001$). The

higher the case-load of a hospital the higher was the chance that patients were stabilized with C-clamp (CC) or external fixation (EF).

Baseline characteristics of patients with and without CC or EF undergoing later surgery are presented in Table 2 (Model 2). Principally, the pattern for this subgroup was the same as seen for all patients. Additionally, the portion of patients being treated by ilio-sacral screw stabilization was analysed in both groups reaching 12.9% and 14.7%, respectively, which was not statistically significantly different.

4.2 EXTERNAL FIXATION OR C-CLAMP (MODEL 1)

Results for model 1 are presented as crude and adjusted ORs for each outcome (general and infectious complications, death) in Table 3. Results from bi-variate analyses indicated that year of surgery and hospital case-load were not associated with any of the outcomes analysed and were not included in the multivariable model. When no odds are reported, the case load was too small for statistically meaningful conclusions.

4.2.1 General complications

Of the 847 (15.4%) patients overall that experienced complications, the proportion in the group that had received a form of emergency stabilization (n=273, 28.5%) was larger than in those treated without (n=574, 12.6%, $p<0.001$). After adjusting for confounding factors, the odds of general complications was 1.25 times higher for patients initially stabilized with C-clamp or external fixation than those without (OR=1.25, 95%CI 1.02-1.53). The odds of general complications was increased in men and complex or vertically unstable type C fractures, elevated with increasing age, ISS, and a maximum displacement >2mm (Table 3).

4.2.2 Infections

Less than 3% of all patients analysed experienced an infection (n=143, 2.6%). Of those patients, a higher proportion of patients receiving a form of emergency stabilization (n=52, 5.4%) experienced infections than those treated without (2.0%, $p<0.001$), with the crude odds of infection 2.8 times higher for those with an emergency stabilization (Table 3). However, after adjusting for confounding factors, the odds of infections was not higher for patients initially stabilized with C-clamp or external fixation than those without (OR=1.28, 95%CI 0.86-1.92). The odds of infections was elevated with increasing ISS, in complex, and type C fractures (Table 3).

4.2.3 Death

There were 306 (5.6%) deaths reported overall, with 102 (10.7%) deaths in the group treated with C-clamp (CC) or external fixation (EF) compared with 204 (4.5%) in the group without emergency stabilization. Although the crude odds indicated a higher chance to die after CC/EF treatment, the adjusted odds for risk of death was actually 32% lower in the CC/EF group (OR=0.68, 95%CI 0.49-0.95). This was caused by the different distribution of the other risk factors. The odds of death increased specifically with increasing age and ISS (Table 3).

4.3 SECONDARY SURGERY (MODEL 2)

Results for model 2 are presented as crude and adjusted ORs for each outcome in Table 4. Results from bi-variate analyses indicated that year of surgery and hospital case-load were not associated with any of the outcomes analysed and were not included in the multivariable model.

4.3.1 General complications, infections, death

Crude OR indicate that patients treated by CC/EF in the first place have a higher risk to sustain general complications, infections and to die. However, adjusted ORs showed no difference. Unevenly distributed but relevant risk factors for general complications were high age, ISS, displacement and the presence of complex fractures, C-type injuries, and laparotomy. This was similar in patients with infection, however, high displacement and ISS were not separate risk factors. Odds indicated the influence of high age, ISS, displacement and the presence of C-type injuries, and laparotomy on mortality.

4.3.2 Subgroup analysis – ilio-sacral screws

This subgroup analysis aimed to investigate the infection rate after stabilization of the pelvis using ilio-sacral screws comparing patients that were primarily treated with C-clamp with a group without this emergency measure. The relative frequency of infections was higher in the patients being treated by C-clamp (20.8% vs 3.2%, Table 5). Caused by the low total amount of cases, the calculation of the adjusted ORs was limited (Table 6). However, based on the available data, the adjusted OR was also higher for this group (OR=4.67, 95%CI 1.06-20.64), indicating the increased risk of infection in this subgroup.

5 DISCUSSION

Patients treated with C-clamp or external fixation were younger, had more C-type fractures, a higher ISS and fracture displacement, more other emergency measures such as pelvic packing and embolization, and more complex fractures (internal organs involved). Since all these factors –the Injury Severity Score (ISS) being the most important one – influence the analyzed outcome measures such as general complications, infections and mortality, the adjusted odds were calculated to evaluate the emergency stabilization as an independent risk factor. By this, it could be shown that mortality was reduced in the group being stabilized with C-clamp or external fixation by 32%, while the risk to suffer from general complications was slightly increased (25%). In the subgroup of secondary surgery, C-clamp or external fixation had no influence on mortality and the risks for complications including infection. However, in the subgroup of ilio-sacral screw fixation following C-clamp use, the risk of infection increased from 3.2 to 20.8%, which partially could be attributed to emergency fixation.

The current literature leaves no doubt that patients in need for any emergency stabilization have a higher risk to die and to suffer from all kinds of complications [12]. However, until now it has not been analyzed whether the emergency treatment itself is effective and/or an independent risk factor for complications. Considering that current guidelines for treatment of hemodynamically unstable pelvic fractures recommend use of pelvic clamp and external fixation [13,14], the need for a clarification of this issue becomes obvious - also regarding a risk-benefit evaluation. Our data confirm recent studies [7] and show an absolute increase in mortality, infection- and complication rate in this population by 2.5-2.8 (crude odds). In contrast to our hypothesis that mortality is leveled out in the groups being treated or not treated by pelvic clamp and/or external fixation, our data for the adjusted odds indicate that mortality is even decreased by 32%, which could directly be attributed to these measures. This confirms the efficacy of these procedures and emphasizes that biomechanical stabilization should be an integral part of the emergency management of unstable pelvic fractures [15].

A look at the subgroup of later operated patients could partially explain this very positive effect. While the crude odds again demonstrated a higher risk for all outcome parameters, after adjusting for confounding factors the results showed no effect at all. This indicates that in the first group the increased mortality of patients without emergency stabilization may be attributed to those who came in such bad conditions to the emergency room that it was decided to stop resuscitation immediately.

The second group describes patients who survived the first peak of death [16]. However, the results emphasize again that there is no increased general risk associated with the pure application of C-clamp or external fixation. Although there are specific complications described after use of C-clamp [17] or external fixation [18], the conclusion can be drawn that on average the complication rate is not higher after emergency stabilization. The clinical consequence of these findings is that, when in doubt, patients should be stabilized because C-clamp and external fixation have a good, life-saving effect and do not harm.

However, there is one exception. Referring to our results analyzing the combination of C-clamp with later ilio-sacral screw implantation, an almost 5-fold increased risk for infection (adjusted odds) needs to be assumed. Considering the low case numbers in this subgroup, it apparently does not affect the results of the analysis of the entire population. Nevertheless, the treating surgeon needs to be aware of this constellation and possibly avoid the combination of pelvic clamp and consecutive ilio-sacral screws whenever possible. Therefore, a general recommendation cannot entirely replace the individual evaluation of the specific situation. It is generally approved that the application of C-clamp or external fixation needs training [19]. All participating centers have experience with treatment of pelvic fractures, and therefore, a certain level of education for the teams in the emergency room is ensured. Nonetheless, our data revealed that patients being acutely stabilized were more likely treated at hospitals with a higher case load. Although this indicates that the more severe cases were treated at larger hospitals, the case load among experienced centers had no influence on any of the examined outcome parameters.

The usual bleeding sources in unstable pelvic fractures comprise the cancellous bone of the fracture sites, the venous plexus of the pelvis, closed or open soft tissue damage and branches of the internal iliac artery. Therefore, it was expected that biomechanical stabilization was very often combined with pelvic packing or selective embolization, which has shown to decrease mortality [20]. In the whole population and the subgroup of later operatively treated patients, pelvic packing (laparotomy) was an independent risk factor for death, which is in line with recently published data [11,21]. Although the procedure has shown to be effective [22], patients with necessity for this procedure had an overall increased risk to die compared to all pelvic fractures.

This analysis has several limitations which are associated with the study design, an evaluation of a single registry. Therefore, some relevant data regarding co-morbidity including Body Mass Index [23], life style or socioeconomic status were not entered, which might potentially bias the complication rate and mortality. Partially, this could be leveled out by correcting for age and gender. Unfortunately, the study lacks long-term data and patient-related outcome measures, which are associated with complications in the course of treatment [24].

6 CONCLUSION

Finally, it may be concluded that initial stabilization of unstable pelvic fractures with C-clamp or external fixation might decrease mortality and is not an independent risk factor for complications after secondary surgery. Only the generally low risk for infection after ilio-sacral screw fixation was increased almost 5-fold after C-clamp use. This means for clinical decision-making that patients should in doubt be stabilized, and the risk for ilio-sacral screw implantation after C-clamp use should be evaluated cautiously.

7 LEGEND

Figure 1: Patient flow chart

Table 1: Baseline characteristics of patients with and without C-clamp stabilization (CC) or external fixation (EF) (Model 1)

Table 2: Baseline characteristics of patients with and without C-clamp stabilization (CC) or external fixation (EF) undergoing surgery (Model 2)

Table 3: Crude and adjusted odds ratios for effect of C-clamp or external fixation for outcomes complications, infection, and death (Model 1)

Table 4: Crude and adjusted odds ratios for effect of C-clamp or external fixation in patients with secondary surgery for outcomes complications, infection, and death (Model 2)

Table 5: Comparison of infections among patients undergoing secondary surgery with IS screws with and without C-clamp (Model 2 subgroup analysis)

Table 6: Crude and adjusted OR for infections among patients undergoing secondary surgery with IS screws with and without C-clamp (Model 2 subgroup analysis)

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9 SUPPLEMENTARY INFORMATION

9.1 AVAILABILITY OF DATA AND MATERIAL

The data generated and analyzed during this study are available from the corresponding author on reasonable request.

9.2 COMPETING INTERESTS

The authors declare that they have no conflict of interest.

9.3 FUNDING

There is no funding source.

9.4 ETHICAL APPROVAL

Data acquisition and analysis were done in accordance with ethical guidelines and approved by our institutional review board (no. 89/09). The trial was registered at the German Clinical Trials Register (no. 00000488).

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None.

2 AUTHORS' CONTRIBUTIONS

HS was responsible for conception and design, analysis and interpretation of data, wrote the manuscript and submitted the final version.

MSL made substantial contributions to interpretation of data; manuscript preparation and gave final approval for the version to be published.

FS supported the conception of the study and data extraction from the registry, contributed to the interpretation of the data, and approved the submitted article.

PCS was involved in the conception of the study, supported the interpretation of the data, and approved the submitted article.

KGB carried out the statistical analysis, substantially contributed to the manuscript especially regarding methods and results, was involved in the conception of the study, critically revised the article draft, and approved the final version.

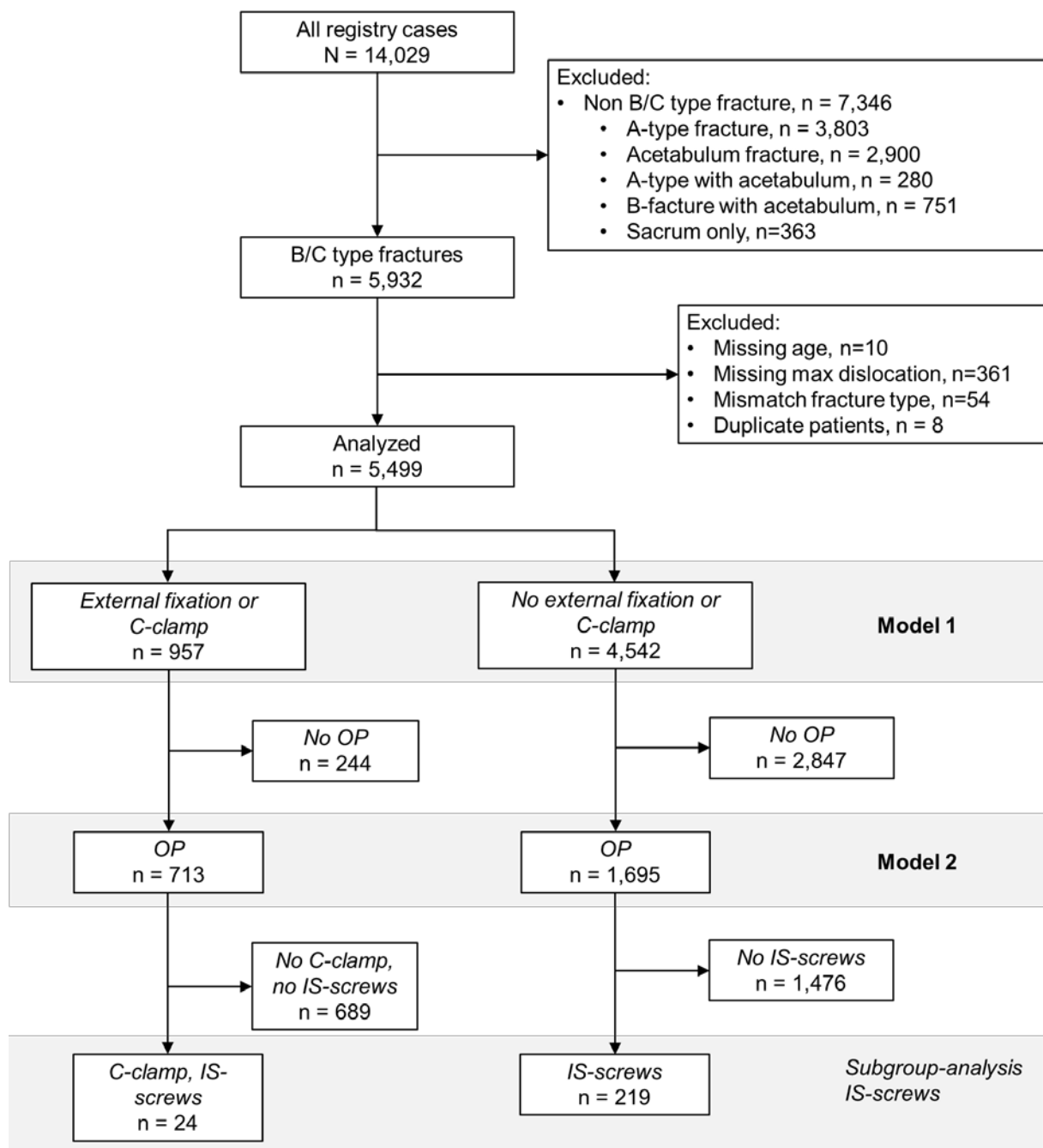


Figure 1: Patient flow chart

Table 1. Baseline characteristics of patients with and without C-clamp stabilization (CC) or external fixation (EF) (Model 1)

	No CC/EF N = 4,542		With CC/EF N = 957		Total N = 5,499		p-value*
	n	%	n	%	n	%	
Age (years)							
Mean (SD)	62.0	(23.8)	44.5	(19.9)	59.0	(24.1)	<0.001
<20	270	5.9	111	11.6	381	6.9	<0.001
20-39	723	15.9	291	30.4	1,014	18.4	
40-59	876	19.3	341	35.6	1,217	22.1	
60-79	1,301	28.6	168	17.6	1,469	26.7	
80+	1,372	30.2	46	4.8	1,418	25.8	
Gender							
male	1,647	36.3	619	64.7	2,266	41.2	<0.001
female	2,895	63.7	338	35.3	3,233	58.8	
Fracture type							
B	3,286	72.4	340	35.5	3,626	65.9	<0.001
C	1,256	27.7	617	64.5	1,873	34.1	
ISS (total score)							
4-14	2,584	56.9	109	11.4	2,693	49.0	<0.001
16-24	1,070	23.6	246	25.7	1,316	23.9	
≥25	888	19.6	602	62.9	1,490	27.1	
Laparotomy							
No	4,512	99.3	802	83.8	5,314	96.6	<0.001
Yes	30	0.7	155	16.2	185	3.4	
Embolization							
No	4,534	30.0	916	95.7	5,450	99.1	<0.001
Yes	8	0.7	41	4.3	49	0.9	
Complex fracture							
No	4,312	94.9	658	68.8	4,970	90.4	<0.001
Yes	230	5.1	299	31.2	529	9.6	
Maximum displacement (mm)							
Mean (SD)	3.4	(5.1)	8.4	(7.8)	4.3	(6.0)	<0.001
<2mm	1,614	35.5	89	9.3	1,703	31.0	<0.001
2mm	1,071	23.6	95	9.9	1,166	21.2	
≥3mm	1,857	40.9	773	80.8	2,630	47.8	
Hospital no. cases							
<500	947	20.9	210	21.9	1,157	21.0	<0.001
500-999	1,844	40.6	286	29.9	2,130	38.7	
1000-1500	1,751	38.6	461	48.2	2,212	40.2	

Values are n, % unless otherwise specified.

*p-value for chi-squared test for categorical values, t-test for mean of continuous variables

Table 2. Baseline characteristics of patients with and without C-clamp stabilization (CC) or external fixation (EF) undergoing surgery (Model 2)

	No CC/EF N = 1'695		With CC/EF N = 713		Total N = 2'408		p-value*
	n	%	n	%	n	%	
Age (years)							
Mean (SD)	53.8	(22.6)	43.7	(18.7)	50.8	(22.0)	<0.001
<20	122	7.2	76	10.7	198	8.2	<0.001
20-39	396	23.4	226	31.7	622	25.8	
40-59	448	26.4	275	38.6	723	30.0	
60-79	491	29.0	113	15.9	604	25.1	
80+	238	14.0	23	3.2	261	10.8	
Gender							
male	819	48.3	476	66.8	1'295	53.8	<0.001
female	876	51.7	237	33.2	1'113	46.2	
Fracture type							
B	788	46.5	207	29.0	995	41.3	<0.001
C	907	53.5	506	71.0	1'413	58.7	
ISS (total score)							
4-14	554	32.7	71	10.0	625	26.0	<0.001
16-24	662	39.1	210	29.5	872	36.2	
≥25	479	28.3	432	60.6	911	37.8	
Laparotomy							
No	1'679	99.1	623	87.4	2'302	95.6	<0.001
Yes	16	0.9	90	12.6	106	4.4	
Embolization							
No	1'691	16.0	685	96.1	2'376	98.7	<0.001
Yes	4	0.9	28	3.9	32	1.3	
Complex fracture							
No	1'527	90.1	490	68.7	2'017	83.8	<0.001
Yes	168	9.9	223	31.3	391	16.2	
Maximum displacement (mm)							
Mean (SD)	5.5	(7.1)	9.1	(8.0)	6.5	(7.6)	<0.001
<2mm	244	14.4	46	6.5	290	12.0	<0.001
2mm	305	18.0	56	7.9	361	15.0	
≥3mm	1'146	67.6	611	85.7	1'757	73.0	
Ilio-sacral screws							
No	1'476	87.1	608	85.3	2'084	86.5	0.236
Yes	219	12.9	105	14.7	324	13.5	
Hospital no. cases							
<500	390	23.0	142	19.9	532	22.1	<0.001
500-999	680	40.1	240	33.7	920	38.2	
1000-1500	625	36.9	331	46.4	956	39.7	

Values are n, % unless otherwise specified.

*p-value for chi-squared test for categorical values, t-test for mean of continuous variables

Table 1. Crude and adjusted odds ratios for effect of C-clamp or external fixation for outcomes complications, infection, and death (model 1)

Adjustment	General Complications		Infection		Death	
	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
Crude						
No C-clamp/ext. fixation	ref		ref		ref	
With C-clamp/ext. fixation	2.76 (2.34 - 3.26)	<0.001	2.81 (1.98 - 3.98)	<0.001	2.54 (1.98 - 3.25)	<0.001
Adjusted						
No C-clamp/ext. fixation	ref	0.032	ref	0.229	ref	0.023
With C-clamp/ext. fixation	1.25 (1.02 - 1.53)		1.28 (0.86 - 1.92)		0.68 (0.49 - 0.95)	
Sex						
Male	ref	0.036	ref	0.362	ref	0.494
Female	0.83 (0.70 - 0.99)		0.85 (0.59 - 1.21)		1.10 (0.84 - 1.44)	
Age (years)	1.02 (1.01 - 1.02)	<0.001	1.01 (1.00 - 1.02)	0.063	1.03 (1.03 - 1.04)	<0.001
ISS (total score)						
4-14	ref	<0.001	ref	0.037	ref	<0.001
15-24	1.93 (1.5 - 2.48)		2.15 (1.19 - 3.9)		1.98 (1.27 - 3.09)	
≥25	3.32 (2.57 - 4.31)		2.00 (1.06 - 3.76)		16.47 (11.22 - 24.18)	
Complex fracture						
No	ref	<0.001	ref	0.001	ref	0.090
Yes	2.62 (2.10 - 3.28)		2.07 (1.34 - 3.20)		1.35 (0.96 - 1.91)	
Fracture type						
B	ref	<0.001	ref	0.001	-	-
C	1.49 (1.22 - 1.83)		2.06 (1.3 - 3.26)		-	
Maximum displacement						
<2mm	ref	<0.001	ref	0.081	-	-
2mm	1.29 (0.99 - 1.68)		1.42 (0.74 - 2.75)		-	
≥3mm	1.86 (1.48 - 2.34)		1.85 (1.05 - 3.27)		-	
Laparotomy						
No	-	-	-	-	ref	<0.001
Yes	-		-		6.11 (3.98 - 9.37)	

P-value for multi-variate model based on likelihood ratio test. Laparotomy was not a confounding factor for complications or infection and was excluded from the final models for these outcomes. Fracture type and maximum dislocation were not confounding factors for death (ref – reference)

Table 4. Crude and adjusted odds ratios for effect of C-clamp or external fixation in patients with secondary surgery for outcomes complications, infection, and death (model 2)

Adjustment	General Complications		Infection		Death	
	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
Crude						
No C-clamp/ext. fixation	ref		ref		ref	
With C-clamp/ext. fixation	1.61 (1.31 - 1.97)	<0.001	1.46 (1.01 - 2.12)	0.046	1.75 (1.03 - 2.99)	0.039
Adjusted						
No C-clamp/ext. fixation	ref	0.179	ref	0.791	ref	0.123
With C-clamp/ext. fixation	1.18 (0.93 - 1.49)		1.06 (0.69 - 1.63)		1.68 (0.88 - 3.22)	
Sex						
Male	ref	0.549	ref	0.788	ref	0.558
Female	0.94 (0.76 - 1.16)		0.95 (0.65 - 1.39)		0.83 (0.45 - 1.53)	
Age (years)	1.02 (1.02 - 1.03)	<0.001	1.01 (1.00 - 1.02)	0.010	1.07 (1.05 - 1.08)	<0.001
ISS total score						
4-14	ref	0.003	ref	0.770	ref	0.002
15-24	1.42 (1.01 - 2.00)		1.25 (0.66 - 2.36)		2.81 (1.12 - 7.09)	
≥25	1.84 (1.29 - 2.62)		1.25 (0.64 - 2.45)		5.09 (2.00 - 12.97)	
Complex fracture						
No	ref	<0.001	ref	0.009	ref	0.150
Yes	2.17 (1.65 - 2.84)		1.92 (1.2 - 3.08)		1.71 (0.83 - 3.51)	
Fracture type						
B	ref	0.004	ref	0.042	ref	0.020
C	1.45 (1.12 - 1.88)		1.63 (1.00 - 2.66)		0.47 (0.25 - 0.88)	
Maximum dislocation						
<2mm	ref	0.010	-	-	-	-
2mm	0.75 (0.48 - 1.16)		-		-	
≥3mm	1.21 (0.86 - 1.71)		-		-	
Laparotomy						
No	ref	0.025	ref	0.026	ref	0.014
Yes	1.68 (1.07 - 2.62)		2.2 (1.13 - 4.29)		3.55 (1.36 - 9.24)	

P-value for multi-variate model based on likelihood ratio test. Maximum dislocation was not a confounding factor for infection or death and was excluded from the final models for these outcomes (ref – reference).

Table 5. Comparison of infections among patients undergoing secondary surgery with IS screws with and without C-clamp (Model 2 subgroup analysis)

Exposure	Infection	No infection
	n (%)	n (%)
IS screws and C-clamp	5 (20.8)	19 (79.2)
IS screws, no C-clamp	7 (3.2)	212 (96.8)
Total	12 (4.9)	231 (95.1)

Table 6. Crude and adjusted OR for infections among patients undergoing secondary surgery with IS screws with and without C-clamp (Model 2 subgroup analysis)

IS-screws sub-group (N=243)		
<u>Adjustment</u>	<u>OR (95% CI)</u>	<u>p-value</u>
Crude		
No C-clamp	ref	
With C-clamp	7.97 (2.21 – 28.69)	<0.001
Adjusted		
No C-clamp	ref	0.042
With C-clamp	4.67 (1.06 - 20.64)	
Sex		
Male	ref	0.450
Female	1.63 (0.46 – 5.76)	
Age (years)	1.00 (0.46 - 5.76)	0.824
Laparotomy		
No	ref	0.053
Yes	7.25 (0.97 - 54.0)	
ref - reference		